

Application Number 10/698,216  
Responsive to Office Action mailed July 26, 2006

### **AMENDMENTS TO THE CLAIMS**

This listing of claims will replace all prior versions and listings of claims in the application.

#### **Listing of Claims:**

Claim 1 (Original): A method for treating fecal incontinence comprising:  
implanting a bulking prosthesis in tissue proximate to an anal sphincter,  
wherein the bulking prosthesis is in a miniature state at the time of implantation and  
assumes an enlarged state after implantation.

Claim 2 (Original): The method of claim 1, wherein the tissue comprises at least one of a  
submucosa and a musculature underlying the submucosa.

Claim 3 (Original): The method of claim 1, wherein implanting the bulking prosthesis  
comprises:

penetrating a mucosa proximate to the tissue with a syringe needle; and  
implanting the bulking prosthesis in the tissue through the syringe needle.

Claim 4 (Currently Amended): The method of claim 1, wherein implanting the bulking  
prosthesis comprises:

drawing a mucosa away from a musculature underlying a submucosa;  
forming a pocket in one of the submucosa ~~and~~ or the musculature; and  
implanting the bulking prosthesis in the pocket.

Claim 5 (Currently Amended): The method of claim 4, wherein drawing the mucosa away  
from the musculature underlying the submucosa comprises applying vacuum pressure to an  
instrument proximate to the mucosa.

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Claim 6 (Currently Amended): The method of claim 4,  
wherein forming ~~[[a]]~~ the pocket in one of the submucosa ~~and or~~ the musculature  
comprises inserting a needle through the mucosa, thereby forming a hole in the mucosa, and  
implanting the bulking prosthesis in the tissue through the hole.

Claim 7 (Original): The method of claim 1, wherein the bulking prosthesis comprises a  
hydrogel.

Claim 8 (Original): The method of claim 1, wherein the bulking prosthesis comprises a  
material that absorbs fluid from the tissue to assume the enlarged state.

Claim 9 (Currently Amended): A system comprising:  
a needle to make a hole through a mucosa proximate to an anal sphincter;  
a tubular instrument having a distal end and an opening at the distal end; and  
a pushing agent to push a bulking prosthesis through the tubular instrument and through  
the hole in the mucosa,  
wherein the bulking prosthesis is in a miniature state at the time of implantation and  
assumes an enlarged state after implantation.

Claim 10 (Original): The system of claim 9, further comprising:  
a source of vacuum pressure; and  
a conduit to deliver the vacuum pressure from the source to the mucosa.

Claim 11 (Original): The system of claim 10, wherein the conduit comprises a distal end with a  
cavity at the distal end to receive the mucosa when the cavity is positioned proximate to the  
mucosa and the vacuum pressure is delivered to the mucosa.

Claim 12 (Original): The system of claim 9, wherein the tubular instrument comprises the  
needle.

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Claim 13 (Original): A device comprising:

a bulking prosthesis in the shape of a partial cylinder having an inner radius,  
wherein the bulking prosthesis comprises a hydrophilic polymer that forms a hydrogel in the presence of water, and

wherein the inner radius of the partial cylinder is sized to conform to close the anus of a patient when the bulking prosthesis is implanted in the patient with an inner surface coaxial with the anus of the patient and when the patient exercises voluntary control over an external sphincter.

Claim 14 (Original): The device of claim 13, wherein the bulking prosthesis has a substantially half-cylinder shape.

Claim 15 (Currently Amended): The device of claim 13, wherein the bulking prosthesis assumes one of a miniature state and an enlarged state, and the bulking prosthesis assumes the shape of the partial cylinder in the enlarged state.

Claim 16 (Original): The device of claim 13, further comprising a Dacron mesh surrounding the hydrophilic polymer.

Claim 17 (Original): The device of claim 13, further comprising a radiopaque material.

Claim 18 (Currently Amended): A device comprising:

a rod-like bulking prosthesis having a sharpened tip,  
wherein the bulking prosthesis comprises a hydrophilic polymer that forms a hydrogel in the presence of water,

wherein the rod-like bulking prosthesis assumes an enlarged state in the presence of water, and wherein the rod-like bulking prosthesis has a length of at least ten millimeters when in the enlarged state.

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Claim 19 (Currently Amended): The device of claim 18, wherein the sharpened tip comprises[[d]] at least one of a conical tip, a needle-like tip ~~and~~ or a wedge-shaped tip.

Claim 20 (Original): The device of claim 18, further comprising a helical thread around the rod-like bulking prosthesis.

Claim 21 (Currently Amended): The device of claim 18, ~~wherein the rod-like bulking prosthesis assumes an enlarged state in the presence of water,~~ and wherein the rod-like bulking prosthesis has a length of at least twenty four millimeters when in the enlarged state.

Claim 22 (Currently Amended): A method for manufacturing a bulking prosthesis comprising:

providing a rod-like bulking prosthesis that comprises a hydrophilic polymer that forms a hydrogel in the presence of water; and

forming a sharpened tip on an end of the bulking prosthesis; and  
machining a helical thread around the bulking prosthesis.

Claim 23 (Original): The method of claim 22, further comprising forming a slot in the bulking prosthesis.

Claim 24 (Canceled).

Claim 25 (Currently Amended): A method for implanting a bulking prosthesis comprising:

implanting a rod-like bulking prosthesis in a miniature state at the time of implantation and having a sharpened tip proximate to an anal sphincter, the bulking prosthesis engaged with an application device; and

withdrawing the application device, wherein the bulking prosthesis assumes an enlarged state after implantation.

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**Claim 26 (Original):** The method of claim 25, further comprising disengaging the bulking prosthesis from application device.

**Claim 27 (Original):** The method of claim 25, further comprising rotating the bulking prosthesis with the application device.